

REMARKS

Applicants respectfully traverse the rejections in the outstanding Office Action, and request that they be withdrawn in view of the following Remarks. Applicant has presented claims 1 and 12 in a way that make it clear that cuvettes are cleansed by different cleaning operations depending upon what assay is scheduled to be next performed therein, and this teaching cannot be found in the cited references, nor is this teaching inherent within the cited references

Claim Rejections –35 USC §112

Claims 1 and 12 have been amended to particularly point out and distinctly claim the subject matter which applicant regards as his invention. The lack of antecedent basis for "identity" has been corrected.

Claim Rejections –35 USC §103(a)

Claims 1 and 12 are rejected under 35 USC 103(a) as being unpatentable over Bell (US 5,679,309) in combination with Sakagami (US 4,785,407) and Jordan (US 4,325,910). The Examiner cites Bell as disclosing "cleaning the used cassette before a first group and a second group of assays have been scheduled to be next performed in the cuvette, and cleaning the (used) cassette when a first group and second group of assays have been previously performed in the cuvette." Applicant respectfully suggests that this is not what Bell discloses for the following reasons.

Bell is attempting to increase analyzer throughput by increasing the frequency at which washing a used cuvette can take place simultaneously with the addition of reagent to a target cuvette. (Col. 3, lines 51-54) This is accomplished by adding a second reagent add station so that reagent can be added to a target cuvette at either of two separate locations on a reaction carousel. (Col. 3, lines 32-33)

As described in FIG. 5, and Col. 3, lines 32-58, because of the nature of the reaction carousel, if the target cuvette is positioned at a first reagent add station, then a first cuvette is parked within the wash station . . . but if the target cuvette is instead positioned at a different reagent add station, then a different cuvette is parked within the wash station. For example:

At Event 1, Cuvette C1 is positioned at reagent add station R1 and a corresponding Cuvette C2 is parked at wash station WS.

At Event 2, Cuvette C1 is instead positioned at reagent add station R2 and a corresponding different Cuvette C3 is parked at wash station WS.

What Bell teaches is to position Cuvette C1 at whichever reagent add station R1 or R2 places a used cuvette ready for washing at the wash station WS. This is described at Col. 10, lines 20-24:

“the processor identifies cuvettes 24 which are available for reactant addition in comparison to the inventory of wash-ready cuvettes. Based upon this comparison, the processor determines whether to add reactant at either the first or second reactant addition points which will locate, during the same park cycle, a wash-ready cuvette at the wash point.”

If neither Cuvette C2 nor Cuvette C3 is ready to be washed, Bell teaches “Do Not Wash Cuvette” (114 in FIG. 5).

The Examiner states that the step of identifying the assays and cleansing the cuvette by different series of cleansing operations is inherent in Bell’s process. Applicant believes that such a conclusion is not valid for the following reasons.

It is well established that, “In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)

A critical and inherent characteristic of Applicant's claimed cleansing method is to "look ahead" to determine the assay yet to be performed in a cuvette yet to be cleansed and to vary the cleansing operation according to whatever assay is identified. This characteristic of the present invention does not necessarily flow from Bell's method because Bell only requires that the processor be able to determine whether to add reactant at whichever reactant addition point which will locate a wash-ready cuvette at the wash point. Since Bell does not need to "examine and identify of assays yet to be performed" in order to conduct his method, it cannot be said that "the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."

The Examiner's rejection based on the theory of inherency therefore fails to meet the criteria set for by the MPEP 2112 IV because, "the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference . . . and may not be established by probabilities or possibilities.'" Bell does not need to determine the assay yet to be performed in a cuvette yet to be cleansed and to vary the cleansing operation accordingly in order to determine where to add reactant in order to "opportunisticly" locate a wash-ready cuvette at the wash point. Therefore the critical "look ahead" step in Applicant's claimed cleansing method is not necessarily present in Bell and therefore the suggestion of inherency is invalid and the rejection is unfounded.

The Examiner cites Sakagami for teaching detecting the dirtiness level of a cuvette and rewashing a cuvette having dirtiness above a threshold level (Col. 5, lines 14-32). The Examiner also cites Jordan for teaching emptying, washing and drying a cuvette and discharging wash liquid (Col. 12, lines 45-48; Col. 13, lines 12-17) and concludes that it would have been obvious for one skilled in the art to use the wash-dry-discharge steps taught by Jordan in the dirtiness detecting scheme taught by Sakagami in Bell et al's, cleaning process to "improve the cleaning process."

Sakagami detects the dirtiness level of a cuvette and rewashes a cuvette having dirtiness above a threshold level. Sakagami does not necessarily need to determine the assay yet to be performed in a cuvette yet to be cleansed and to vary the cleansing

operation accordingly in order to detect dirtiness level. Jordan teaches emptying, washing and drying a cuvette and discharging wash liquid. Jordan does not necessarily need to determine the assay yet to be performed in a cuvette yet to be cleansed and to vary the cleansing operation accordingly in order to wash and dry a cuvette. Therefore neither Sakagami nor Jordan teach, and it is not inherent within either reference, to "look ahead" to see what assay will be next performed in a used cassette that is to be cleaned and adjust the cleaning operation accordingly, as is claimed by Applicant.

Consequently, the proposed modification of Bell using the Sakagami and Jordan references fail to teach Applicant's cuvette washing scheme in which different washing conditions are employed depending upon the identify of the assay scheduled to be next performed therein. Accordingly, Applicant respectfully submits that the claims are allowable over the prior art, and requests removal of the rejection of the present invention as being unpatentable under 35 USC 103(a).

Conclusion

Applicants believe that this application contains patentable subject matter and that the foregoing amendments provide a basis for favorable consideration and allowance of all claims; such allowance is respectfully requested. If any matter needs to be resolved before allowance, the Examiner is encouraged to call Applicant's representative at the number provided below.

Respectfully submitted,



Leland K. Jordan
Agent for Applicant
Registration No. 36,560

DADE BEHRING INC.
1717 Deerfield Road, Box 778
Deerfield, IL 60015-778
Phone: (847) 267-5365